REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-5, 7-12 and 14-16 are pending. Claims 1-5 and 7-12 are amended, claims 6 and 13 are cancelled and claims 14-16 are added, without prejudice.

No new matter is added by this amendment.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations in the claims is found throughout the specification.

II. 35 U.S.C. §101 REJECTION

Claims 9-13 were rejected under 35 U.S.C. §101 as allegedly reciting an improper process claim; and claims 1-7 were rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. The rejections are traversed.

The amendments to the claims render the rejections moot. Consequently, reconsideration and withdrawal of the Section 101 rejections are respectfully requested.

III. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION

Claims 1-13 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed.

The amendments to the claims obviate the rejection. Consequently, reconsideration and withdrawal of the Section 112, second paragraph, rejections are respectfully requested.

IV. 35 U.S.C. § 112, FIRST PARAGRAPH, REJECTION

Claims 1-13 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Applicants disagree.

The amendments to the claims, however, render the rejection moot. More specifically, claim 1 is directed to an isolated nucleic acid molecule comprising at least 17 nucleotides of SEQ ID NO: 1 – 7 or the completely complementary sequences thereof. Also encompassed are isolated nucleic acid molecules with at least 90% identity to the isolated nucleic acid molecules disclosed in detail. Therefore, the isolated nucleic acid molecules of claim 1 recite a defined upper length limitation and the complementary sequence is the entirely complementary sequence.

Applicants clearly have possession of the instant invention. To this end, the Examiner is respectfully reminded of the state of the law in *In re Herschler*, 591 F. 2d 693, 700 (C.C.P.A. 1979), where the predecessor court to the Federal Circuit explained that:

> The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied upon, the specific subject matter later claimed by him; how the specification accomplishes this is not material. The claimed subject matter need not be described *In haec verba* to satisfy the description requirement. It is not necessary that the application describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that appellants invented processes including those limitations.

In re Herschler, 591 F. 2d 693, 700 (C.C.P.A. 1979) (internal citations omitted).

Against this background, Applicants believe that the instant specification contains sufficient information to make a skilled artisan appreciate that Applicants had possession of the claimed invention at the time of filing. Therefore, possession of the claimed invention clearly exists.

Consequently, reconsideration and withdrawal of the Section 112, first paragraph, rejection are respectfully requested.

V. 35 U.S.C. § 102 REJECTIONS

Claims 1-5 and 9-12 were rejected under 35 U.S.C. §102(b) as being anticipated by Accession Number Q20004 in WO 91/18997; claims 1, 2, 6 and 7 were rejected under 35 U.S.C. §102(b) as being anticipated by WO 91/18997 to Matteucci et al.; and claims 1-5 were rejected under 35 U.S.C. §102(b) as being anticipated by an article by Domann et al. The rejections are traversed.

The amendments to the claims render the rejection moot. It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Against this background, the Section 102 rejections must fail. Claim 1 is directed to at least 17 successive nucleotides of the nucleic acid molecule, none of which are known from the

prior art. Further, none of the cited documents teach or enable the instantly claimed 17 nucleotide amino acid sequences which are useful as oligonucleotides for polymerase chain reaction or hybridization to distinguish *Listeria monocytogenes* from other *Listeria* strains.

Consequently, reconsideration and withdrawal of the Section 102 rejections are respectfully requested.

VI. 35 U.S.C. § 103 REJECTIONS

Claims 8 and 13 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Matteucci et al. in view of an article by Ahern; claims 6, 7 and 9-12 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over an article by Rossen et al. in view of the Domann et al. article; and claims 8 and 13 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Rossen et al. in view of Domann et al. and further in view of Ahern. The rejections will be collectively addressed and are respectfully traversed. The cited documents do not teach, suggest or motivate a skilled artisan to practice the instantly claimed invention.

The Federal Circuit is quite clear that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed**

invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Against this background, the Section 103 rejections are defective. Applicants point out that WO 91/18997 relates to sequence-specific cross-linking agents which bind to the major groove of duplex DNA. WO 91/18997, however, does not provide any teaching or suggestion of *Listeria monocytogenes*, let alone of sequences specific for the identification of bacteria of this species. Similarly, Ahern does not teach or suggest that isolated nucleic acids are provided in kits.

The Examiner appears to believe that simply because pre-made reagents and kits are convenient and easy to buy, it would be *prima facie* obvious to one skilled in the art to provide oligonucleotides of WO 91/18997 in a kit. But nowhere does the Examiner identify any scientific principle or theory found in the references to suggest the claimed invention. Further, motivation is lacking in the cited documents for leading a skilled artisan to practice the instantly claimed invention.

With respect to the purported combination of Rossen et al. and Domann et al., Applicants stress that Rossen et al. does not disclose the sequence of a single oligonucleotide specific for *Listeria monocytogenes*. Rossen et al. only states that "two primers, LM14 and LM16, fulfilled the requirement to hybridizing to all *L. monocytogenes* isolates" (page 147, last paragraph, lines 5 – 7). It is pointed out that only LM14, for which no concrete nucleotide sequence is given, hybridizes only to *Listeria spp*., whereas LM16 also hybridizes to a *Listeria innocua* isolate. The false positive LM16 is shown in detail Fig. 1, panel B, of Rossen at al.

In contrast thereto, all the claimed oligonucleotides of the present invention are specific for *Listeria monocytogenes*, as PCR primers and for hybridization purposes. Further, Rossen et al.

use primer sets derived from sequences located downstream of the hlyA gene (abstract), while the present invention uses specific oligonucleotides of the metalloprotease gene (mlp), which is completely independent of the hlyA gene as it contains its own promoter, ribosome binding site, transcription and translation initiation site and its stop codon.

Further, the Examiner is respectfully reminded that "obvious to try" is not the standard by which an obviousness rejection should be based. And as "obvious to try" would be the only standard that would give the instant Section 103 rejections credence, the rejections must fail as a matter of law.

Moreover, it was surprisingly and unexpectedly discovered that unexpectedly high sequence variations in the hlyA flanking intervals of different *Listeria monocytogenes* strains are present. The Examiner is respectfully directed to page 5 of the specification. Therefore, it was highly unexpected that individual oligonucleotides could be identified which are absolutely specific for *Listeria monocytogenes* without any cross-reactivity as shown in Rossen et al.

Thus, the instant invention exhibits unexpected results and superiority over the art and, thus, rebuts any holding of *prima facie* obviousness. In other words, the unexpectedly high sequence variation in the *hylA*-flanking intervals of different *L. monocytogenes* strains disclosed on page 5 of the specification belies the Examiner's assertion that selection of the inventive subsequences of the *hylA*-flanking interval would have been obvious. Therefore, even if it was so held that a person with ordinary skill in the art would have been motivated to practice the instant invention from a reading of the cited documents, a point Applicants do not concede, the instant specification clearly rebuts such a holding since the cited documents do not suggest that Applicants' invention would exhibit such superior and unexpected results. The claimed invention, as a result, is unobvious.

Consequently, reconsideration and withdrawal of the Section 103 rejections are warranted and respectfully requested.

CONCLUSION

By this Amendment, the instant claims should be allowed; and this application is in condition for allowance. Favorable reconsideration of the application, withdrawal of the rejections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,
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